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(Diane Blevins)

Docket No.: 532212000623

(PATENT)

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Thomas L. CANTOR

Application No.: 10/617,489

Confirmation No.: 4476

Filed: July 10, 2003

Art Unit: 1641

For: METHODS, KITS AND ANTIBODIES FOR

Examiner: J. Cheu

DETECTING PARATHYROID HORMONE

### DECLARATION OF THOMAS L. CANTOR PURSUANT TO 37 C.F.R § 1.132

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

- I, Thomas L. Cantor, in my individual capacity, hereby declare as follows:
- 1. I am the inventor of the above-referenced patent application, and am familiar with the contents thereof.
- 2. This application is a continuation-in-part (CIP) of serial number 09/344,639, filed on June 26, 1999, and now issued as U.S. Patent No. 6,743,590, which is a CIP of serial number 09/231,422 (the '422 application), filed on January 14, 1999, now issued as U.S. Patent No. 6,689,566 (the '566 patent).
- 3. Figure 5 of the '422 application mentions a tracer antibody that is referred to as "PTH 1-8 Antibody as Tracer." The term "PTH 1-8 antibody" was used to refer to this antibody

Application No.: 10/617,489 2 Docket No.: 532212000623

because I then believed the antibody had been isolated by Dr. Ping Gao and his co-workers using a PTH 1-8 peptide for affinity purification of the antibody. When Figure 5 was created and when the '422 application was filed, I believed that such a tracer antibody was used for the experiment represented by Figure 5.

- 4. In a deposition which occurred on August 27, 2003, related to the case Nichols v. Scantibodies on Nichols's U.S. patent No. 6,030,790, the attorney questioning me said, "Well, isn't it true that 1-9 meant that you used a 1-9 peptide to affinity purify your antibody?" In response, I stated: "I believe Dr. Gao used a peptide that contained 1-9."
- 5. In connection with the case Scantibodies v. Immutopics on Scantibodies' 566 patent, I became aware that the peptide in question was purchased from a supplier, as was the normal practice at Scantibodies: such peptides are typically purchased, rather than made. I also saw the invoice for the particular peptide used for affinity purification of the antibody that was used to generate the data represented by Figure 5 of the patent application serial number 09/231,422, which was filed on January 14, 1999. The invoice states that the peptide purchased for that purpose was a peptide containing PTH 1-9.
- 6. Based on the above facts, I believe that the antibody used to generate the results described in Figure 5 of serial number 09/231,422 should have been referred to as a PTH 1-9 antibody. In the current application, Figure 5, which was retained from the earlier '422 application, still refers to the antibody as "PTH 1-8 Antibody." Accordingly, I believe Figure 5 of the current application should be corrected to refer to the antibody as "PTH 1-9 Antibody."

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

3

March 6, 2006

Date

Thomas L. Cantor



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form and the use of es-sion-ist \-'pre-

2: ROMANCE 5 de-emphasizes tra-by more pragmatic b(2-)r2-,li-z2m\n ic] (1882): a Neo-

relating to the latest

thyü-\ adj (1896) y contraception) zho-ni-zom\ n by a streptomyces eat local infections t NEW] (1898) 1: a t is found in minute ELEMENT table 2 a proportion of ne ination provided by

eon 2 : extremely

to, or affecting the st month after birth

natus, pp. of nasci to

branch of medicine s of newborn infants

nber of a group es-is — neo-Nazi adj

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ir. Gk neophytos, fr. - + phyein to bring SELYTE 2: NOVICE!

.: the formation of

ew growth of tissue

of, relating to, or elating to neoplasti-

fr. ne- + plastique ti-cist \-sist\ n 1: Platonism modin, post-Aristotelian, rld as an emanation te soul is capable of the similar to ancient la-\ adj — Neo-pla-

(1937): a synthetic ne, characterized by pecial-purpose cloth-

: a movement esp. in ect depiction of low-p-re-al-is-tic \-,re->

Puerto Rican living Yorker and puertowho lives on the U.S. erto Rico

(ca. 1909) : a movemedieval Scholasti-

tine (as in physostig-form of its bromide H<sub>22</sub>N<sub>2</sub>O<sub>6</sub>S esp. in the n the diagnosis and

Gk teinein to stretch larval or immat maturity during the

3k neôterikos, fr. Gk ng — more at NEW]

ographic region that eau of Mexico ical region hat is selected subse-

preexisting type that

so Ne-pal-is [Hindi val] (ca. 1885) 1: a

native or inhabitant of Nepal 2: an Indo-Aryan language spoken in Nepal — Nepall adj
ne-penthe \no-\text{Pentl}. the \n \n \n \text{L nepenthes.} fr. Gk nepenthes. neut. of nepenthe \no-\text{Penthes penthes banishing pain and sorrow, fr. ne-not + penthos grief, sorrow, akin to Gk pathos suffering — more at No. PATHOS] (1580) 1: a potion used by the ancients to induce forgetfulness of pain or sorrow 2: something capable of causing oblivion of grief or suffering — nepen-the-an \-the-an\ adj
neph-e-line \no-fa-len\ also neph-e-lite \-\lit\ n \ [F nepheline, fr. Gk nephele cloud — more at NEBULA] (ca. 1814): a hexagonal mineral that is a usu glassy crystalline silicate of sodium, potassium, and aluminum common in igneous rocks — neph-e-lin-lic\ \ne-fa-li-nit\ n \ [ISV] (ca. 1863): a silica-deficient igneous rock having nepheline as the predominant mineral — neph-e-lin-lic\ \ne-fa-la-\ ni-tik\ adj
neph-e-lom-e-ter \ne-fa-la-\ ni=m-tor\ n \ [Gk nephele\ cloud + ISV \-meter] (1884) 1: an instrument for measuring the extent or degree of cloudiness 2: an instrument for determining the concentration or particle size of suspensions by means of transmitted or reflected light — neph-e-lo-met-ri-c\ \n-eph-e-lo-met-ri-c\ \n-ep

velocity of clouds

nephroscotory of clouds nephro-comb form [NL, fr. Gk, fr. nephros — more at NE-phritis]: kidney (nephric) (nephrology) ne-phrec-to-my \ni-frec-to-mize \-niz\ v | nephro-comb form [NL, fr. Gk, fr. nephros — more at NE-phritis]: kidney (nephric) (nephrology) ne-phrec-to-my \ni-frec-to-mize \-niz\ v | nephro-comb form [NL, fr. Gk, fr. nephros — more at NE-phritis]: kidney — ne-phrec-to-mize \-niz\ v | neph-ric \ni-fri\ nadj (1887): RENAL ne-phrid-i-dum \ni-fri\ nadj (1887): RENAL ne-phrid-i-dum \ni-fri\ nadj (1887): RENAL ne-phrid-i-dum \ni-fri\ nadj (1887): nephros; fr. its formerly being worn as a remedy for kidney diseases] (1794): a compact tremolite or actinolite that is the commoner and less valuable kind of jade and that varies in color from white to dark green or black ne-phriti-ic \ni-fri-tis\ naj (1580) 1: RENAL 2: of, relating to, or affected with nephritis ne-phritis \ni-fri-tis\ naj (1580) 1: RENAL 2: of, relating to, or affected with nephritis no to ME nere kidney] (1580): a cute or chronic inflammation of the kidney caused by infection, degenerative process, or vascular disease ne-phrol-o-gy \ni-frai-1-j\vec{c}\ n (ca. 1842): a branch of medicine concerned with the kidneys — ne-phrol-o-gist \-jist\ n (ca. 1842): a single excretory unit of the vertebrate kidney. ne-phrol-o-gist \-jist\ n (ca. 1900): an abnormal state of the kidney; esp: one associated with or secondary to some other pathological process — neph-ro-path-ic \ne-fra-'pa-thik\ adj ne-phrosis \ni-fro-ss\ n [NL] (1916): a noninflammatory disease of

adj ne-phro-sis \ni-\fro-sss\ n [NL] (1916): a noninflammatory disease of the kidneys chiefly affecting function of the nephrons; also: NEPHROTIC SYNOROME—ne-phrot-ic \-\frac{1}{15}-\frac{1}{16}\ adj or n nephro-stome \no-\frac{1}{15}-\frac{1}{15}-\frac{1}{16}\ nephrostoma, \frac{1}{15}-\frac{1}{15}-\frac{1}{15}\ nephrostoma \frac{1}{15}-\frac{1}{15}-\frac{1}{15}\ nephrostoma \frac{1}{15}-\frac{1}{15}-\frac{1}{15}\ nephrostoma \frac{1}{15}-\frac{1}{15}-\frac{1}{15}\ nephrostoma \frac{1}{15}-\frac{1}{15}\ nephrostoma \frac{1}{15}-\frac{1}{15}\ nephrostoma \frac{1}{15}-\frac{1}{15}\ nephrostoma \frac{1}{15}\ nephrostoma \frac{1}{15}-\frac{1}{15}\ nephrostoma \frac{1}{15}\ nephrostoma \fr

cal nephridium

stomal (1888): the chilated tunnel-shaped coelomic opening of a typical nephrotic syndrome n (1939): an abnormal condition that is marked by deficiency of albumin in the blood and its excretion in the urine due to altered permeability of the glomerular basement membranes neph-ro-tox-ic \ne-fra-'täk-sik\ adj (1902): poisonous to the kidney (\pi drugs); also: resulting from or marked by poisoning of the kidney (\pi effects) — neph-ro-tox-ic-i-ty\-täk-si-sa-ie\ n ne plus ul-tra \nā-plas-si-l-tra, nā\ n [NL. (go) no more beyond] (1638) 1: the highest point capable of being attained: ACME 2: the most profound degree of a quality or state nepo-tism \ne-pa-\ti-tz-m\ n [F népotisme, fr. 1t nepotismo, fr. nepote nephew, fr. L nepot-, nepos grandson, nephew — more at NEPHEW] (1670): favoritism (as in appointment to a job) based on kinship — nepo-tistic \ne-pa-\tistik\ adj
Nep-tune \ne-p-\tistik\ adj

irom the sun — see Planet table — Nep-tu-ni-an \nep-tu-ne-on, 'tyii-\adj adj nep-tu-ni-um \nep-tii-ne-om, -'tyii-\adj nep-tii-ne-om, -'tyii-\adj nep-tii-ne-om, -'tyii-\adj nep-tii-ne-om, -'tyii-\adj nep-tii-ne-om, -'tyii-\adj nep-tii-ne-om, -'tyii-\adj nep-tii-ne-om, -'tyii-ne-om, -'tyi

ogy ne-rit-ic \n>-'ri-tik\ adj [ISV, perh. fr. NL Nerita, genus of marine snails] (1891): of, relating to, inhabiting, or constituting the belt or region of shallow water adjoining the seacoast ne-rol \ner-ol, 'nir-\ n [ISV ner- (fr. neroli oil) + 1-of] (1869): a liquid alcohol C<sub>jb</sub>H<sub>j0</sub>O that has a rose scent and is used in perfumery ner-oli oil \ner-o-le-\ n [F néroli, fr. li neroli, fr. Anna Maria de La Trémoille, princess of Nerola f11670] (1849): a fragrant pale yellow essential oil obtained from orange flowers and used esp. in cologne and as a flavoring

nerts \'norts\ n pl [alter. of nuts] (ca. 1932) slang: NONSENSE NUTS -

nerts \'narts\ n pl [alter. of nuts] (ca. 1932) slang; NONSENSE. NUTS — often used interjectionally ner-va-tion \, nar-va-shan\ n (1849); an arrangement or system of nerves; also: VEMATION
| nerve \ narv\ n [L nervus sinew, nerve; akin to Gk neuron sinew, nerve, nene to spin — more at NEEDLE] (14c) 1: SINEW. TENDON (strain every \times 2 : any of the filamentous bands of nervous tissue that connect parts of the nervous system with the other organs, conduct nervous impulses, and are made up of axons and dendries together with protective and supportive structures 3 a: power of endurance or control: FORTITUDE. STRENGTH b: ASSURANCE, BOLDNESS: also: presumptuous audacity: GALL 4 a: a sore or sensitive point b pl: nervous disorganization or collapse: NERVOUSNESS 5: VEIN 3 6: the sensitive pulp of a tooth sym see TEMERITY | nerve w nerved; nerv-ing (ca. 1749): to give strength or courage to: supply with physical or moral force nerve cell n (1858): NEURON: also: CELL BODY nerve center n (1868) 1: CENTER 2c 2: a source of leadership, organization, control, or energy (the financial nerve center of the nation) nerve cord n (1877) 1: the pair of closely united ventral longitudinal nerves with their segmental ganglia that is characteristic of many elongate invertebrates (as earthworms) 2: the dorsal tubular cord of nervous tissue above the notochord of a chordate that comprises or develops into the central nervous system nerved 'vnarvd' adi (1800) 1 a: VENNED (a ~ wing) b: having

develops into the central nervous system nerved \'norvo\ adj (1800) 1 a: \text{VENED (a \simeq \text{wing}) b: having veins or nerves esp. of a specified kind or number \to \text{used in combination (fan-nerved leaves) 2: showing courage or strength nerve ending n (ca. 1890): a structure forming the distal end of a nerve axon.

nerve fiber n (ca. 1847): any of the processes (as axons or dendrites) of a neuron

nerve gas n (1940): an organophosphate chemical weapon that inter-

of a neuron nerve gas n (1940): an organophosphate chemical weapon that interferes with normal nerve transmission and induces intense bronchial spasm with resulting inhibition of respiration nerve growth factor n (1962): a protein that promotes development of the sensory and sympathetic nervous systems and is required for maintenance of sympathetic neurons nerve impulse n (1900): the progressive physicochemical change in the membrane of a nerve liber that follows stimulation and serves to transmit a record of sensation from a receptor or an instruction to act to an effector—called also nervous impulse nerve-less \hat\text{'nar-vis}\text{ adj} (1742) 1: lacking strength or courage: Feeble 2: exhibiting control or balance: PoiseD, COOL—nerve-less-ly adv—nerve-less-ness nerve net n (1904): a network of nerve cells apparently continuous with one another and conducting impulses in all directions; also: a primitive nervous system (as in a jellyfish) consisting of such a network nerve—rack-ing or nerve-wrack-ing \hat\text{'nar-v-ra-kin}\text{ adj} (1812): extremely trying on the nerves (a ~ ordeal)
nerve trunk n (1851): a bundle of nerve fibers enclosed in a connective tissue sheath

tive tissue sheath her-vos-i-ty \nor-'v\u00e3-s-t\u00e3\u00e

nervous \'nor-vos\ adj (14c) 1 archaic: SINEWY, STRONG 2: marked by strength of thought, feeling, or style: SPIRITED (a vibrant tighter packed ~ style of writing) 3: of, relating to, or composed of neurons 4 a: of or relating to the nerves; also: originating in or affected by the nerves (~ energy) b: easily excited or irritated: JUMPY c: TIMID. APPREHENSIVE (a ~ smile) 5 a: tending to produce nervousness or agitation: UNEASY (a ~ situation) b: appearing or acting unsteady, erratic, or irregular used of inanimate things syn see VIGOROUS — nervous-ly adv — nervous-ness n nervous breakdown n (1905): an attack of mental or emotional disorder esp. when of sufficient severity to require hospitalization nervous Nel-lie or nervous Nel-ly \-'ne-le\ n, pl nervous Nellies often cap 1st N-[fr. the name Nellie] (1926): a timid or worrisome person

often cap 1st N [fr. the name Nellie] (1926): a timid or worrisome person nervous system n (1740): the bodily system that in vertebrates is made up of the brain and spinal cord, nerves, ganglia, and parts of the receptor organs and that receives and interprets stimuli and transmits impulses to the effector organs — compare CENTRAL NERVOUS SYSTEM. PERIPHERAL NERVOUS SYSTEM. AUTONOMIC NERVOUS SYSTEM. PERIPHERAL NERVOUS SYSTEM ner-vure \nor-var'o 17. Fr. nerf sinew, fr. L nervaig (1816): VEIN 3 nervy \nor-ve\ adj nervi-er; -est (1607) 1 archaic: SINEWY, STRONG 2 a: showing calm courage: BOLD b: marked by effrontery or presumption: BRASH 3: EXCITABLE NERVOUS — nervi-ly \-v-v-l\(\cap{c}\) adv — nervi-ness \-v\(\cap{c}\)-ons\(\cap{c}\) now, fr. ne not + scire to know — more at NO. SCIENCE] (1612): lack of knowledge or awareness: IGNORANCE — ne-scient \-sh\(\cap{c}\)-ont, -s\(\cap{c}\)-ont (3\) lack of knowledge or awareness: GNORANCE — ne-scient \-sh\((\cap{c}\)-ont, -s\(\cap{c}\)-ont, -s\(\cap{c}\)-ont, os\(\cap{c}\) now nore at NO. SCIENCE] (1612): lack of knowledge or awareness: CNORANCE — ne-scient \-sh\((\cap{c}\)-ont, -s\(\cap{c}\)-ont, -s\(\cap{c}\)-ont, os\(\cap{c}\) now nore at NO. SCIENCE] (1612): lack of knowledge or awareness incess \ nos\(\cap{c}\) nos\(

\2\ abut \2\ kitten, F table \2r\ further \a\ ash \\a\ ace \\a\ mop, mar \au\out \ch\chin \c\ bet \e\easy \g\ go \i\ hit \i\ icc \j\ job  $\n$  sing  $\n$  go  $\n$  law  $\n$  th\ thin  $\n$  the  $\n$  loot  $\n$  foot \y\ yet \zh\ vision \a, k, ", ce, ce, ue, ue, ve, r\ see Guide to Pronunciation

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